FY 2006
PROGRAM ELEMENT EVALUATION REPORT

OF THE

GROWING AREA CLASSIFICATION ELEMENT
SHELLFISH SANITATION PROGRAM
DEPARTMENT OF MARINE RESOURCES
STATE OF MAINE

PREPARED BY

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ON

October 12, 2006

PROGRAM ELEMENT EVALUATION REPORT

STATE: Maine

DATES OF EVALUATION: May 22 - 26, 2006 and June 12 - 16, 2006

PROGRAM ELEMENT EVALUATED: Growing Area Classification

A. Status of Previous Program Evaluation

The FY 2005 evaluation of the Maine Department of Marine Resources (DMR) Growing Area Program found that the DMR was in compliance with the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). The FY 2005 evaluation focused on all recently completed Triennial Reports for all growing areas. No administrative deficiencies were cited during the FY 2005 program evaluation per Chapter IV of the NSSP MO. No program wide deficiencies related to shoreline survey activities or the shoreline survey database were noted. There were also no specific recommendations made as a result of the evaluation.

B. Status of Current Evaluation

1. Total Number of Growing Areas Evaluated

The Maine Department of Marine Resources monitors 45 separate Shellfish Management Areas. Twelve of the Shellfish areas were selected to be evaluated. The number of evaluations is based upon a representative sampling plan designed to provide a 95 percent probability of detecting a 20 percent or greater defect level. The selection of the 12 growing areas was performed by Peter Koufopoulos, the Northeast Regional Shellfish Specialist. Mr. Koufopoulos chose 12 shellfish growing areas which had not been previously reviewed as part of a prior audit. The selected growing areas are listed below.

Shellfish Management Areas

West - Boothbay Harbor Office	East - Lamoine State Park Office
WF - Fortunes Rocks	EB - North Eggemoggin Reach
WH - Spurwink River	EF - Western Blue Hill Bay
WK - Quahog Bay	EJ - Gouldsboro Bay
WN - Sheepscot River	EM - Pleasant Bay
WP - Boothbay Harbor	EQ - Little Kennebec River
WU - St. George River	ET - Cobscook Bay

2. Program Area Level of Compliance

a) Sanitary Survey

General

The Maine DMR follows the NSSP Model Ordinance (MO) regarding the completion timeframes for all required reports. Currently the staff is required to complete the Sanitary Surveys every 12 years, the Triennial Reports every 3 years and the Annual Updates every year. Internal DMR policy states that all reports are to be formatted to meet the requirements of the MO. All Annual Updates are scheduled to be completed by February 28th each year for the previous calendar year. Conditional area management plans are re-evaluated on an annual basis. Information gathered from the management plan review is included in the Annual Update and used to support any changes in classification.

All conditionally managed areas that were reviewed during this evaluation period were closed according to the criteria established in the Conditional Area Management Plan. However the verification of those standards was not completed for some of the marina conditional areas. The determination as to the presence or absence of the boats did not coincide with the actual day the area either opened or closed for the season.

DMR also closes Approved waters during emergency conditions, typically after heavy rainfall events. The DMR staff receives great pressure from the commercial shellfish harvesters to reopen closed areas as soon as possible. In lieu of shellfish tissue sampling, areas closed due to management plan violations are normally closed for a minimum of fourteen days after the event. In order to be more responsive to the harvesters demand, the DMR has decided to incur the additional expense of sampling both shellfish growing waters and shellfish tissues in an attempt to open the shellfish harvesting areas more quickly whenever possible and appropriate. A closed area will reopen only after acceptable water samples and/or shellfish tissue results are received and evaluated. This sampling also supplements ongoing studies to document relationships between fecal coliform bacteria levels in the water and fecal coliform bacteria levels in the surrounding shellfish. Any correlation made could reduce the effort of future sampling and also allow the fourteen-day cleansing period to be shortened.

Required

Sanitary Surveys are completed on all Shellfish Management Areas prior to the harvest of shellstock for human consumption. A Sanitary Survey along with its associated shoreline survey is used to determine the proper classification of an area as Approved, Conditionally Approved, Restricted, Conditionally Restricted or Prohibited.

Written Sanitary Survey reports were present and complete for all 12 management areas reviewed. DMR follows the format described in the NSSP MO Guidance Document Growing Area @.03. The reviewed survey reports did have all of the required sections and subsections. The various sections within the report have very detailed information; including charts, graphs and pictures to further enhance the discussion.

Once the shoreline survey results are reviewed and the water quality data is analyzed the DMR complete the written sanitary survey report. The report details the findings of the staff in the specific Shellfish Management Area. All failing water quality stations are placed within classifications (other than approved) which would prevent direct market harvest except under certain circumstances.

While reviewing the 2006 Annual Update for Shellfish Management Area WN two sample stations were noted (31.00 and 87.00) as having failing water quality while being located directly on or adjacent to a closure boundary line. The location of the boundary line does not afford the necessary buffer based on the information available. The boundary lines should be reassessed scientifically and the new lines should be moved to the most appropriate location to protect public health. Similar boundary line concerns were noted in the following areas: Area WU (closure around stations 14.5 and 16 in Broad Cove and a closure around station 45.5 in Otis Cove), Area EF (closure around stations 1.9 and 2 in Herrick Bay, stations 21 and 23 in McHeard and Curtis Coves and station 25 in Morgan Bay), Area EQ (closure around station 5 in the western branch of the Little Kennebec Bay) and Area ET (closure around station 42 in East Stream, station 60 in Denny's River, station 69 near Burnt Island, station 81 in Pennamaquan River, station 91 in Sipp Bay and station 100.2 in Half Moon Cove)

Performance

The DMR schedules Sanitary Surveys to be completed once every 12 years for each Shellfish Management Area. The water quality staff does recognize that if a Sanitary Survey (or a Triennial Review) is not completed within the specified time frames then the Shellfish Management Area shall be placed in the closed status pending completion of the report.

Triennial Report --

The DMR Shellfish Program completes Triennial Reports every three years in order to supplement and update information found within the Sanitary Survey. The triennials are more comprehensive than the Annual Updates. The triennials are intended to be a thorough review of all known pollution sources; an actual reassessment of their impact on the shellfish growing waters.
The Triennial Reports were the focus of the FY 2005 evaluation. The reports were reviewed for completeness and accuracy based on field observations. The reports were reviewed by the Shellfish Specialist while they were in draft form.

Comments were forwarded to the appropriate growing area staff member for concurrence and inclusion within the report when necessary.

The file review conducted as part of this evaluation found that two Triennial Reports which were due to be completed by the end of calendar year 2005 still had not been completed. Triennial Reports for growing areas WA and WS remained incomplete as of the week of June 12, 2006. The file review revealed that the necessary field work had been completed; however the actual writing of the Triennial Reports had not been finished. The staff members were allowed one week to complete the written report or the area affected would have to be closed per the NSSP.

Annual Update --

Annual Updates are designed to review important performance standards, sampling data and pollution source information to determine if a downward trend in water quality is occurring. The Annual Updates were reviewed as part of this evaluation and found to be complete; thus they are in compliance with the minimum requirements of the NSSP MO.

The review of the annual reports revealed greater detail in the narrative sections of the updates; this is an improvement over past years. The growing area staff members, with direct oversight from management, continue to review and improve upon the reports outline (template) to help ensure consistent reporting by all staff members.

Sampling requirement --

The DMR Shellfish Program operates under the Systematic Random Sampling Scheme and creates the sampling schedule in December of each year for the next calendar year. The schedule is completed far enough in advance to ensure sufficient variation with respect to environmental conditions. A master sampling schedule file is maintained for each of the two Division offices. The water quality staff is required to document any changes to the sampling calendar and obtain management approval prior to any change.

While reviewing the sampling calendar several instances were noted where the original sampling date was changed. Original sampling dates should only be changed for reasons such as: hazardous weather conditions, equipment failure, other high priority public health incidents, etc. When a change must occur the reason for the change, along with the new sample date, should be noted in the sample calendar master file.

During the file review it was noted that the sampling schedule for Shellfish Growing Area WH (Spurwink River) had been skewed to accommodate

conditional area sampling due to a seasonal closure. There are ten sample stations within this growing area and only three stations are within the conditional area boundary. It appears that in order to meet the requirement to sample conditional area stations six times per year while in the open status the program sampled all stations during the conditionally open period from December 1st to May 31st leaving the remaining month's minimally sampled, if at all. That leaves five sample stations which are approved and open for year-round harvest sampled in only a six month window of time.

The Boothbay Harbor Office water quality reports completed in 2006 for activities which occurred in 2005 noted that three of the six Shellfish Management Areas reviewed did not have all of the required samples collected. Area WH had two stations with only five out of six (5/6) samples collected; Area WK had three stations with 5/6 and one station with 4/6 samples collected; and Area WN had 14 stations with only 5/6 samples collected.

Conditional Area Management Plans --

The DMR Shellfish Program uses the conditionally approved and conditionally restricted classifications in order to allow Maine shellfish harvesters a greater opportunity to harvest shellfish otherwise not accessible under the traditional classification process. The program uses the conditional area classification for the following conditions when the water quality variations are predictable: wastewater treatment plant, marina, rainfall and season.

A review of the seasonal conditional area justification for Shellfish Management Area WH revealed little correlation between water quality scores and time of year. The data showed several elevated scores throughout the year making the condition seem less than predictable. The seasonal conditional area in Area WH may need to be amended or removed completely.

During the file review of Area WK the 2006 report issued for this area was an Annual Update. The update recommended a classification change for Gun Point Cove. Station 44 is the only station located in the small cove. The analytical statistics were run on the last 30 samples and the station failed to meet the approved criteria with a geomean of 6.5 and a P90 of 49.8/100 ml. The update recommends making the cove conditional based on season. The proposed dates for open direct market harvest are October 1 thru April 30. The main issue noted is that when the data is sorted for the time the area is in open status there are only five samples out of 30 which fall October 1 thru April 30. One sample occurred in December 2001, three of the samples were collected in October of three different years ('02, '03, '04) while the last was collected November 2005.

Based on the analytical data available it does not appear there is enough information upon which to make an accurate assessment of what the water quality

is doing from month to month while the area is in the open status. Unless additional information can be obtained Gun Point Cove should be classified as Restricted.

Brickyard Cove, also in Area WK, was treated similarly based on sample station WK 59.0 failing with a water quality score of 8.9/60.9. The Annual Update recommended this cove be open October 1 thru April 30 based on a seasonal correlation with analytical data. The data review showed that 15 of the past 30 samples were collected during the proposed open status of the conditional area. The predictability of the pollution is in question since four of the 15 samples showed levels above 14 MPN, the highest being 240 MPN while the area would be in the open status.

The Growing Area WN file review of the conditional area management plan (CAMP) showed that state closure 22 (conditional area based on a marina) is placed in the closed status May 15th to September 15th of each year. The predictable pollution source for this area would be the presence of the boats in the marina with the ability to discharge human sewage. The DMR staff verified on May 2nd that the number of boats with heads in the marina did not exceed ten. The staff did not conduct any other boat count prior to the area being placed in the closed status and therefore the staff have no way to know whether the number of boats with heads exceeded ten from May 3rd to May 14th.

Like Growing Area WN, Area EB has conditional areas based on marinas. The Center Harbor and Benjamin River CAMP discuss when the conditional area changes status from open to closed and back again. According to the review, after the Center Harbor area reopened on October 1, 2005 24 days had past before a field verification was completed to show the boats actually were out of the water and the area meet the performance standards for reopening (ten boats or less with heads remaining in the area).

b) Shoreline Survey Requirements

All potential and actual pollution sources have been evaluated by the DMR and documented in the initial Sanitary Survey Reports for each shellfish growing area. Pollution source information is constantly updated throughout the year by both boat and vehicle. The pollution source information gathered throughout the year is then incorporated into the next appropriate report. Specific pollution concerns are individually discussed below as they are found in the reports along with noted details from the shoreline survey database:

Domestic/Industrial/Agriculture Wastes

Many of the 45 Shellfish Management Areas have Wastewater Treatment Plants that discharge directly into shellfish waters; or the plants affect the growing area by discharging into rivers which drain into the growing areas. DMR has placed buffer zones around all of the discharges located in the coastal zone. Many of the treatment plant outfalls have completed hydrographic studies. Outfalls waiting for these studies to be completed have buffer zones based on mathematical calculations using worst case situations and untreated or partially treated sewage.

There are very few industrial discharges along the coast of Maine. Most of them are located in heavily populated areas which have an existing closure due to other influences. Agricultural runoff is not a problem for many growing areas along the coast. The bold rocky coast of Maine is not conducive for large amounts of livestock. There are vast blueberry fields near the coastal waters; however stream sampling has not shown their overland runoff to pose a problem to the surrounding water.

Domestic Waste - Individual Sewage Disposal Systems

As is often the case in coastal Maine, the subsurface soil composition is not always adequate for establishing proper leach fields. Consequently the majority of the recently installed septic systems are designed to have raised bed leach fields. Prior to the use of this more modern sewage disposal system, the coastal area of Maine relied on a system known as an Overboard Discharge (OBD). The Maine Department of Environmental Protection (DEP) currently licenses, regulates, and inspects these OBDs which are approved sewage treatment systems consisting of a sand filter or mechanical treatment system and a chlorine disinfection unit used to treat discharges of sanitary waste from residential and commercial facilities. If the system is designed properly the chlorinated waste is discharged through a pipe extending to below the low tide mark. OBDs have been regulated in Maine since the late 1970s when direct discharges of untreated wastes were banned. New OBDs are prohibited by law however, existing systems that remain licensed and inspected may continue to be used until the owner is offered a grant from the Maine Overboard Discharge Program administered by the DEP. The program offers money to replace the OBD with a traditional septic system; or find and/or design an alternative system that can be installed. The Maine Overboard Discharge Program awards grants based upon a priority system. OBDs located in the most productive shellfish habitats are the highest priority for removal. If any of the OBDs are found not to be working properly then that system is given priority for replacement.

Existing OBD outfalls do have a prohibited closure zone placed around the end of the pipe. The size of the closure zone is based on calculations generated from the permit information. The water depth (for dilution, including viral), permitted

flow rate and the average fecal coliform concentration for a chlorinated system of this type are all factors used to establish a buffer zone to protect public health.

Drainage Ditches - Stormwater Runoff

Stormwater runoff from drainage ditches, creeks and streams are considered to have the largest impact on water quality in the growing areas of Maine. Stormwater transports pollutants, including fecal coliform bacteria, from many of the indirect pollution sources in the drainage basin, to the growing area. The impact of these outfalls is evaluated by strategically placing sampling stations in these ditches, creeks and streams and also at their confluence with the growing area.

As with many indirect sources of pollution, the overall impact from these specified drainage-ways on the growing area is only known through the review of long-term historical data. Most of the data centers on heavy rainfall events. This is due to the fact that these drainage-ways, which may be dry most of the year, will begin to flow, becoming a conduit for potential pollution to reach the viable shellfish areas. Actual flow rates are now being collected and are used to generate fecal loading calculations.

Wildlife/Domestic Animals

General descriptions of migratory waterfowl and typical populations of other regional wildlife are included in the shoreline survey reports. Regional wildlife populations are considered significant contributors to the fecal coliform levels in the growing areas during rain events within the local drainage basin. Migratory waterfowl are contributors also; however, the overall impact of wildlife, in general, is ultimately unknown.

Domestic animals within the management areas are typically dogs and cats. Few homes have horses and fewer still have other barnyard type animals as domesticated pets.

Marinas

All marinas within close proximity to Approved shellfish harvesting waters were evaluated as the focus of the FY 2002 Growing Area Program Evaluation. The evaluation noted that the marina community within Maine will only operate part of the year due to adverse regional weather. The operating procedures the marinas have in place provide an excellent opportunity for the shellfish growing waters to be accessible, at least part of the year, to direct market harvest through the use of conditional management plans.

The closure zones were created by the state using volumetric calculations and re-verified during the evaluation. The basic formulas used were found in FDA guidance issued in June 1989, which describes the proper procedure when establishing a precautionary closure zone around a marina for the purpose of protecting public health.

Radionuclides/Metals

There were no known sources of radionuclides or heavy metals impacting any of the growing areas evaluated. There is some metals data in the central files for those growing areas near industrial or more heavily populated areas. General statements to this effect are made in each of the growing area reports.

c) Illnesses

The State of Maine has not been the original source of shellfish associated with any *Vibrio vulnificus (V.v.)* illness in the past three years. Maine was the possible source of two *Vibrio parahaemolyticus (V.p.)* illnesses in the past three years.

- A 34 year old female, consumed six raw oysters as part of a sample platter on June 26, 2004 with illness onset the same day. The victim recovered from the illness. The oysters on the sample platter were from five different locations (four different states and 1 foreign country). A portion of the suspect oysters were from the Damariscotta River in Maine.

- A 67 year old male, consumed boiled/steamed clams as a meal on August 27, 2005 with illness onset the next morning. No other seafood was reportedly consumed. The victim died on August 30, 2005. The clams were purchased by the victim from a truck located at one of the Portland, Maine fishing piers. The clams had no identification; therefore the harvest area is unknown.

- A 21 year old male, consumed lobster along with steamed mussels and clams on July 29, 2006 at two different restaurants (lunch and dinner) with illness onset the next day. Six different shellfish dealers provided the clams and mussels within two days prior to consumption to the two dealers. All shellfish tags reviewed showed the product was harvested only from Maine state waters.

No additional V.p. illnesses have been reported since the July 29, 2006 illness. The three illnesses above were isolated cases with no other individuals outside their party becoming ill. The DMR recently updated their state regulations and require harvesters to deliver shellstock to dealers within 16 hours of harvest. This is currently more restrictive than the previous requirement which allowed harvesters to follow Time-Temperature Matrix Option 3 - Level 2.

d) Marine Biotoxin Evaluation

The DMR has developed a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas. The blue mussel, *Mytilus edulis*, is used as the indicator species when monitoring for paralytic shellfish poisoning (PSP). PSP levels in mussels usually become toxic two weeks before soft-shelled clams, *Mya arenaria*. Mussels are sampled weekly from April through October along the entire coast. Additional samples are collected as conditions dictate whether to further delineate a closure or simply assess an area that has experienced a slight rise in PSP concentrations.

Maine adheres to the PSP international toxic level standard of 80 micrograms per 100 g of whole shellfish tissue. Current state law allows the DMR to immediately close any area that contains toxins or contaminants known to be a public threat. This type of emergency closure effectively revokes all shellfish licenses; it also grants authority to embargo, confiscate and destroy contaminated or potentially contaminated shellfish.

When a closure is deemed necessary, the director of the biotoxin monitoring program will draft a legal notice and a map and notify the state's shellfish program director. The director of the biotoxin monitoring program will then submit the legal notice to the Commissioner's office. Once the legal notice has been signed by the Commissioner or his/her designee, the director of the biotoxin monitoring program will update the Shellfish Sanitation Hotline with the new information and send out an e-mail version to the distribution lists, while the shellfish program coordinator works on sending out copies of the legal notice by fax to all affected towns, marine patrol offices, and municipal shellfish wardens. The shellfish program coordinator also forwards the notice in local newspapers. The municipal shellfish wardens will post notifications in highly visible public places, and marine patrol officers will then conduct intense patrols of the affected harvesting areas by water and from land.

The DMR has established policy to assist in the coordination of a contaminated shellfish product recall. DMR requires the certified dealer to contact the receiving state's control authority and provide all pertinent recall and tagging information. The dealer will request the suspect product to be destroyed or returned to the state of origin for further assessment.

The DMR is in close contact with the Canadian shellfish authorities and other state officials along the eastern seaboard. Information regarding increased toxicity in a growing area and changes in phytoplankton populations is shared and analyzed. Collaboration by the DMR, USFDA and the University of Maine Cooperative Extension resulted in the creation of a volunteer-based phytoplankton monitoring program in 1996. There are currently 62 active volunteers sampling

46 sites statewide who report weekly to the DMR on their findings from plankton tows performed at stations assigned by the DMR.

e) Shoreline Survey Database

The Shellfish Management Areas within Maine are quite large. The water quality staff members have been forced to break areas into smaller, more manageable sized areas when conducting any shoreline survey reconnaissance. As a result, it may take several years for the pollution source assessment along the entire growing area shoreline to be completed.

The shoreline survey database is set up to be very comprehensive. The eastern-half of the state routinely updates the shoreline database from their field data sheets. It was noted that only a portion of the western-half of the state's shoreline survey information has been entered into the computer. Currently hardcopies of their shoreline data must be reviewed to determine if correlations exist between water quality and identified pollution source locations.

3. Current Findings

a) State Program Deficiencies

i. During the review of the Shellfish Management Area files it was noted that two Triennial Reports scheduled for completion in calendar year 2005 had yet to be completed by the time of this audit. Although the field work had been completed the final version of the report had not been submitted to management for review and approval. The DMR did not follow the NSSP-MO and place the growing area in the closed status at the end of 2005 when the report was not completed. Chapter IV@.01.C.3.(a)(b)

ii. During the review of the Shellfish Management Area files it was noted that water quality sampling runs were being adjusted to accommodate conditional area sampling. The samples were collected during a specific timeframe and were not collected year-round. This approach left Approved sample stations which were open year-round without the year-round data to support the classification. Chapter IV@.02.F.6.b.ii

iii. During the review of the Shellfish Management Area files it was noted that 25% of the growing waters did not have the minimum number of samples collected per the Systematic Random Sampling regime. Chapter IV@.02.F.6.b.iii

iv. During the review of the Shellfish Management Area files it was noted that multiple conditional areas have been created which do not correlate the water quality scores to the environmental condition which would adversely affect the area. Chapter IV@.02.@.03.C.1.c

v. During the review of the Shellfish Management Area files it was noted that not all conditional area management plans contained procedures for immediate notification to the DMR when performance standards or criteria are not met. This was specifically noticed in some marina conditional area management plans with regards to the actual presence of boats verse the opening and closing dates (change in status) of the conditional area. Chapter IV@.03.C.2.f

vi. During the review of the Shellfish Management Area files it was noted that in some of the growing areas there were closed area boundaries around failing water quality stations which were established in an arbitrary fashion. The closure lines need to be based on scientific principals such as analytical data from other water quality stations or dilution calculations when sample stations are not possible due to overland topography or basic accessibility. Chapter IV@.01.C.(5)(6)

b) Recommendations

i. The FDA recommends that whenever a change to the original master systematic sampling calendar occurs that along with the new date of sampling the reason for the change be added to the calendar master file in order to justify the date change.

ii. The FDA recommends that the conditional area management plans be reviewed to ensure that the pollution upon which the conditions are set is truly predictable.

4. Corrective Actions taken by the State

a) The seasonal conditional area in the Spurwink River (C13) was reclassified as restricted on June 5, 2006.

b) The seasonal conditional area in Brickyard Cove [formerly C18-F, now C18] was reclassified as prohibited on August 8, 2006.

c) The seasonal conditional area in Gun Point Cove (C17-C) was reclassified as restricted on October 3, 2006.

5. Action Plans Requested

a) A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the state will comply with the requirement to complete all required reports within the timeframes specified in the Sanitary Survey section of Chapter IV.

b) A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the state will comply with the requirement to sample all water quality stations year-round based on the Systematic

Random Sampling Scheme and not bias the sampling to a time of year due to a nearby conditional area.

c) A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the state will comply with the requirement to collect the minimum six (6) samples per year per station as required in the bacteriological standards section of Chapter IV.

d) A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the state will comply with the requirement to ensure that the analytical data used to establish a conditional area does indeed correlate to the actual conditions used to determine if a shellfish growing area should be in the open status during specific periods throughout the year.

e) A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the state will comply with the requirement to establish procedures for immediate notification to the Authority when performance standards are not met.

f) A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the state will comply with the requirement to establish sufficiently sized closures around failing water quality stations and how the state will document the justification as to where the closure line will be placed in relationship to the failing station.

6. Accomplishments

General

- The Public Health Division was successful in securing an additional $250,000 of general fund dollars for the budget which included 7 permanent seasonal Conservation Aide positions which were awarded as part of their supplemental budget. The new positions were all cross trained to do field work for Biotoxin and Water Quality (WQ) (sampling and shoreline survey). One was assigned to the Lamoine Laboratory; one was assigned to Washington County (duty station); and one was assigned to the quahog boat (but available to do other duties as assigned). Three positions were assigned to the Boothbay facility. The 7th position was assigned to a duty station in the mid-coast region (Belfast, Searsport area) to be available for duty at either Lab as needed. This is an especially attractive position for the DMR in that it can serve many purposes. It can be available to sample areas currently neglected (Stonington/DeerIsle/Castine/ Vinalhaven/North Haven/ Belfast/Rockland) during the Biotoxin season filling a huge gap in data. This alone may answer the "PSP sandwich" question (area of low toxin concentrations surrounded by areas of high toxin concentrations). Also,

this position can easily be available to transport samples and supplies between Labs.

Laboratory (testing)

- The Division was also successful in securing overhead costs as part of the supplemental budget along with one time funding from ME DEP to outfit both WQ laboratories with membrane filtration (MF) equipment. Mercuria Cumbo is also working with the FDA on the conversion factor for the data in switching from the MPN test to the MF test. It will be 5 years for the DMR to move away from the calculation for MPN to the calculation for MF. The DMR will work on some educational materials to post on their website and mail to municipalities and shellfish committees on what the "new" numbers will mean and describe the timeline. As of Monday, August 21, 2006 the laboratories officially began the membrane filtration method and discontinued the MPN 3 - tube dilution method. The new method does not provide results any faster but allows the DMR to process more samples in less time and saves staff time on clean up and media preparation. The membrane filtration method will also give more precise data.

- Amy Fitzpatrick just completed notifying all Public Health Division lab (biotoxin and WQ) and field staff (biotoxin and WQ) of a change in work hours and schedules. The change will allow the labs to run 7 days a week from April to November in the event of emergency situations like flood, PSP and rainfall closures. This change was brought about because over the last several years the fishing industry has voiced a concern that sample collection, lab analyses and the opening and closing of areas was limited to Monday through Friday. The shellfish industry's work is not limited to Monday through Friday. Their previous operating schedule had delayed the harvesters ability to work when they have to wait a weekend (or longer) for sample collection and lab analyses in order for DMR to reopen an area.

Biotoxin

- Data analysis of the 2005 *Alexandrium sp*. harmful algal bloom (HAB) event demonstrated that it was the most intense HAB event in Maine in at least thirty years, infecting at least eleven different species of shellfish and other marine organisms. Despite this fact, the DMR Biotoxin program managed to adequately define closure areas in order to protect public health (there were no illnesses reported due to PSP from any shellfish originating in Maine), and the areas in the open status allowed commercial shellfish harvesters in Maine to land more than 7 million pounds of various types of shellfish during this event.

- Darcie Couture has developed a new Index for measuring the severity of Alexandrium HAB events (Red Tide) from season to season. The Index takes into account several factors of a Red Tide event, including total biomass toxicity,

number of different species toxified, duration of bloom event, and number of unique stations toxified. Dr. Don Anderson from Woods Hole Oceanographic Institute (WHOI) has also commented that he is intrigued by the plot of the index, as it is consistent with a hypothesis they have had at WHOI that, over the last 15 or 20 years, toxicity was declining until the last few years, and that we now may be in this "new regime" of more frequent and higher intensity blooms in the western Gulf of Maine.

- Increased training on how to properly collect a Biotoxin sample was given to periphery staff (Area Biologists, Marine Patrol and Shellfish Wardens). In addition, the same training was given to a few key individuals in geographically significant areas of the coast, who were then issued a “Special License,” (after a full background check was conducted by Marine Patrol), which allowed them to collect Biotoxin samples for DMR from closed areas of the coast on a weekly basis. This focused training made it possible for these individuals to collect additional samples for the program. In many cases, these samples were vital in fine-tuning the closure lines, leaving as much commercially important areas in the open status as possible, while still adequately protecting public health.

- Darcie Couture was invited by the Chair of AOAC Task Force on Marine and Freshwater Toxins, to join the international group, the AOAC Presidential Task Force on Marine and Freshwater Toxins. This is a large group of experts on marine and freshwater toxins, and stakeholders who have a strong and practical interest in the development and validation of these methods. Marine toxins and freshwater toxins require extensive monitoring programs and have a significant economic and human health impact. Although there is a strong and global need for improved testing methods for these toxins, the demand for new, officially validated methods has not been met. This Task Force will address this need by focusing efforts, setting priorities, and identifying economic and intellectual resources. Ms. Couture's background, experience, expertise and recognition will serve the group well. At this time they are also inviting her to join subgroups of interest to her state (saxitoxins, diarrhetic toxins, etc).

7. New or Emerging Problems

   No new or emerging problems were noted as part of this evaluation.

8. Technical Assistance and/or Training Requested by the State

   In the fall of 2005 the DMR requested an advanced growing area course as part of the annual training requests submitted by the states and sent to FDA’s training branch. As a result of their interest the Public Health Division hosted the FDA Advanced Growing Area Course from March 6th-10th, 2006 at the Boothbay Harbor Lab. Shellfish managers from Canada (Eastern Canada and Ottawa), the NE region and other Maine

environmental agencies (DEP) attended. As of mid-October 2006, no new training requests have been received from the DMR for FY 2007.

9. Summary of the State's response to FDA evaluation

   The ME DMR concurs with the findings of this evaluation and remains committed to maintaining and improving compliance with the NSSP. We truly believe that the newly acquired resources will help resolve most of our current program deficiencies.

10. Conclusion

    It was noted in the FY 2004 Growing Area Evaluation that within two years, in order to stay in compliance with the minimum requirements of the program, harvest areas may need to be reclassified as prohibited resulting in reduced acreage available for harvest. This was due to the fact that the DMR seemed unable to complete all of the required activities necessary to maintain an effective public health program by meeting all of the NSSP requirements.

    The FY 2005 Growing Area Evaluation documented the same condition within the DMR, specifically citing the level of effort needed to administer the program verse the number of employees available to carry out the required tasks. The workload continued to increase; whether from new Federal-State regulation changes or the special requests for additional water quality work from towns throughout coastal Maine.

    This evaluation has determined that the Maine DMR Shellfish Growing Area Classification Program has been unable to comply with the minimum requirements found within the NSSP-MO. There were six aspects of the water quality classification requirements in Chapter IV that the program failed to meet. One more notable deficiency dealt with the requirement to complete reports within a specified period of time. The MO states that if Triennial Reports are not completed with the 3-year time frame then the growing area shall be placed in the closed status [until complete]. The DMR did not close Growing Area WA or WS when the Triennial Reports were not completed within the specified time. If the state had followed the requirements and closed both areas the following would have been affected: Area WA - three shellfish license holders and the state's only shellfish depuration plant; Area WS - approximately 180 shellfish license holders and multiple shellfish aquaculture license holders.

    The FDA believes that a complete internal audit of each of the state's 45 Shellfish Growing Areas is necessary to determine the Shellfish Program's actual level of compliance. The FDA finds a clear relationship between the number of water quality staff members and the amount of program work completed in a timely fashion.